

**IN THE UNITED STATES DISTRICT COURT FOR THE  
MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION**

<b>RUTH SMITH, Individually and as Widow</b>	)	
<b>for the Use and Benefit of Herself and the</b>	)	
<b>Next of Kin of RICHARD SMITH, Deceased,</b>	)	<b>Case #: 3:05-00444</b>
	)	<b>Judge Trauger</b>
<b>Plaintiff,</b>	)	
	)	
<b>-against-</b>	)	
	)	
<b>PFIZER INC., PARKE-DAVIS,</b>	)	
<b>a division of Warner-Lambert Company</b>	)	
<b>and Warner-Lambert Company LLC,</b>	)	
<b>WARNER-LAMBERT COMPANY,</b>	)	
<b>WARNER-LAMBERT COMPANY LLC and</b>	)	
<b>JOHN DOE(S) 1-10,</b>	)	
	)	
<b>Defendants.</b>	)	

**PLAINTIFF’S MEMORANDUM IN OPPOSITION TO DEFENDANTS’  
MOTION *IN LIMINE* TO EXCLUDE ALL EVIDENCE OF OR REFERENCES  
TO WARNER-LAMBERT COMPANY LLC’S GUILTY PLEA OR ANY  
RELATED GOVERNMENT INVESTIGATIONS OR AGREEMENTS**

Plaintiff Ruth Smith, as the Widow for the use and benefit of herself and the next of kin of Richard Smith, deceased, by and through here attorneys, respectfully requests that this Court deny in its entirety Defendants’ motion *in limine* to exclude all evidence of or references to Warner-Lambert Company LLC’s guilty plea or any related government investigations or agreements. Docket No. 124. Such information is relevant to various salient issues in this litigation, including Defendants’ knowledge of Neurontin’s off-label use by individuals like Richard Smith; Defendants’ corresponding duty to warn of risks of suicidality and depression; and Defendants’ failure to provide an adequate warning. Moreover, pursuant to Fed. R. Evid. 403, the probative value of such evidence is critical to Plaintiff’s case in chief. Plaintiff would

be severely prejudiced if same is not presented to a jury, and such prejudice would outweigh any alleged prejudice to Defendants.

## INTRODUCTION

### **THE SCOPE OF THE WARNER-LAMBERT FELONY CHARGE AND GUILTY PLEA IS INTERTWINED WITH RICHARD SMITH'S OFF-LABEL MEDICAL CONDITION AND USE OF NEURONTIN**

Warner-Lambert pleaded guilty to two felony charges which include facts and allegations that form the basis of Plaintiff's suit arising from Richard Smith's death. First, Warner-Lambert pleaded guilty to illegally marketing Neurontin off-label indications:

in interstate commerce . . . into Massachusetts and elsewhere for *neuropathic pain*, for bipolar disorder, . . . and for other Unapproved Uses. No approval, pursuant to 21 C.F.R. § 355, . . . was in effect with respect to Neurontin for these uses. [Emphasis added.]

See Information, Count One, ¶¶ 37-38, United States of America v Warner-Lambert Company LLC, May 13, 2004, attached as Exhibit A to the Declaration of Kenneth B. Fromson, Esq., submitted herewith.

Second, Warner-Lambert pleaded guilty to misbranding Neurontin, specifically that it introduced Neurontin:

. . .into interstate commerce . . . into Massachusetts and elsewhere for neuropathic pain, for bipolar disorder,... and for other Unapproved Uses, and which was misbranded within the meaning of 21 CFR § 352(a), in that Neurontin's labeling lacked adequate directions for such uses.

Fromson Decl., Ex. A, Count Two, ¶¶ 39-40 (emphasis added).

The Information articulates in paragraph 9 other medical conditions for which Warner-Lambert illegally marketed Neurontin and for which its label lacked adequate directions, including *other uses* and “and “*other unapproved uses*.”

Richard Smith suffered from pain, an unapproved use for the prescription of Neurontin. Nevertheless, he was prescribed and took Neurontin for his pain. The label, which lacked adequate directions for use and was provided to prescribing doctors as set out in the criminal Information, was in all relevant respects the same label that was provided for Neurontin when Mr. Smith's doctors prescribed it for him and when he took it. It was the same label that was provided with Neurontin when Mr. Smith committed suicide. That label did not warn prescribing doctors of increased risks in off-label patients of suicide, suicide attempt, or of other suicide-related adverse events that were associated with the use of Neurontin by patients such as Mr. Smith, who suffered from pain. Defendant Warner-Lambert by its guilty plea admitted that the label did not provide adequate directions for such "Unapproved Uses." Ex. A, ¶ 40.

The plea agreement executed by Warner-Lambert stated: "Warner-Lambert expressly and unequivocally admits that it committed the crimes charged in the Information. Warner-Lambert agrees that the facts set forth in the Information are true." *See* Plea Agreement, Fromson Decl., Ex. B, page 2 of 9.

## **ARGUMENT**

### **POINT I**

#### **DEFENDANTS' GUILT BOTH AS TO MARKETING NEURONTIN IN TENNESSEE FOR OFF-LABEL USES, AND FOR HAVING INADEQUATE DIRECTIONS FOR USE IN THE NEURONTIN LABEL, IS PROBATIVE OF DEFENDANTS' NEGLIGENCE**

"Relevant evidence" means evidence having any tendency to make the existence of any "act that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Moore's Fed. Rules Pamphlet 2009; Fed. R. Evid. 401. Defendants' guilt as to marketing Neurontin in Tennessee for off-label uses, with admitted inadequate directions, is relevant to Plaintiff's negligence, failure-to-warn, and negligent

pharmacovigilance claims against Defendants. *See In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 618 F. Supp. 2d 96, 114 (D. Mass. 2009). Judge Patti B. Saris succinctly described the heightened duty to warn that a pharmaceutical manufacturer bears when it engages in off-label marketing of a drug:

Based on the reasoning of this caselaw, the Court concludes that a manufacturer of a pharmaceutical has a duty to disclose to physicians and patients material facts about the risks of the drug, *particularly when it is engaged in off-label marketing for uses not approved by the FDA*, if it knows that the plaintiff and/or his prescriber does not know or cannot reasonably discover the undisclosed facts.

*Id.* at 110 (emphasis added).

The manufacturer's knowledge of off-label use with its drug is inextricably intertwined with a manufacturer's duty to disclose material facts about risks with the drug. While off-label prescribing by physicians is not itself improper, a manufacturer with knowledge of both extensive off-label use and material facts about risks inherent with taking the drug (e.g., depression and suicide), has a duty to take action. Here, Warner-Lambert's guilty plea is an admission as to Defendants' knowledge of the off-label use and Defendants' knowledge that Neurontin lacked adequate directions in its labeling (i.e., a failure to warn). Consequently, Defendants' guilty plea is probative of Defendants' negligence.<sup>1</sup>

## POINT II

### **ADMISSIBILITY OF THE GUILTY PLEA AND RELATED GOVERNMENT INVESTIGATION OR AGREEMENTS IS CONSISTENT WITH THE FEDERAL RULES OF EVIDENCE AND CASELAW**

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<sup>1</sup> At the trials in both *Bulger v. Pfizer Inc.*, D. Mass. No. 1:07-11426-PBS, and in the action against Defendants by Kaiser Foundation Health Plan, Inc. and Kaiser Foundation Hospitals, Judge Saris held that Warner-Lambert's guilty plea was admissible. *See* Defs. Mem. in support of a similar motion in *Shearer v. Pfizer Inc.*, D. Mass. No. 04-10981, Docket No. 2558 at 4. But Defendants contended in *Shearer* that "unlike *Kaiser*, this case does not concern the off-label marketing of Neurontin, as Plaintiff has been unable to draw any causal connection from alleged off-label marketing to Mr. Shearer's Neurontin prescriptions." *Id.* at 4 n.5 (the trial settled before the *Shearer* motion was decided). However, this Court has not dismissed Plaintiff's claims that Defendants wrongfully promoted Neurontin for off-label uses, and Plaintiff fully intends to proceed with this claim at trial.

Defendants have failed to bring to the Court's attention the statutes, rules, and case authorities that specifically provide that evidence of a final felony conviction is admissible, although Defendants have, however, admitted that their wrongful conduct had been elevated to felony status. *See* Docket No. 125 n.4.

Federal Rule of Evidence 803(22) expressly provides that evidence of a final judgment, entered after a trial or upon a plea of guilty, adjudging a person guilty of a crime punishable by death or imprisonment in excess of one year, is admissible to prove any fact to sustain the judgment. *See* Judgment in a Criminal Case, Fromson Decl., Ex. C.

Federal Rule of Evidence 803(22) has been adopted in Tennessee State courts as well. *See, e.g., State v. Thompson*, 285 S.W.3d 840, 852-53 (Tenn. 2009); Tenn. R. Evid. 803. Further, "it is well-established that a criminal conviction may be used in a subsequent civil action to prove issues that were determined in the prior criminal trial. *Grange Mut. Cas. Co. v. Walker*, 652 S.W.2d 908, 910 (Tenn. App. 1983)." *Marion v. Bowling*, C/A No. 03A01-9906-CV-00229, 1999 Tenn. App. LEXIS 764, at \*7 (Tenn. App. Nov. 22, 1999).

The plea of guilty to violation of a statute is the best evidence of violation of that statute. Defendants pleaded guilty to two separate statutory violations, i.e., of 21 U.S.C. §§ 331(d), 333(a), and 355(a), illegal marketing of a drug, and 21 U.S.C. §§ 331(a), 331(a)(2) and 352(f)(1), misbranding an illegally marketed drug. Defendants spin this as technical violations of Food and Drug Administration regulations, but the violation of those regulations is a federal crime and is evidence of Defendants' negligence.

In addition, the admissibility of the guilty plea in a civil case following the conviction is specifically authorized by 18 U.S.C. § 3664(l),<sup>2</sup> which provides that:

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<sup>2</sup> This statute was at the time of the Warner-Lambert conviction in 18 U.S.C. § 3664(e).

[A] conviction of a defendant for an offense involving the act giving rise to an order of restitution shall estop the defendant from denying the essential allegations of that offense in any subsequent Federal civil proceeding or State civil proceeding, to the extent consistent with State law, brought by the victim.

While no restitution order was entered in the underlying criminal case, that is because over \$400,000,000 in restitution was paid on entry of the plea and as a condition of the guilty plea, and therefore no order was necessary. *See* Warner-Lambert Sentencing Memorandum, Fromson Decl., Ex. D; Plea Agreement, Fromson Decl., Ex. B.

Finally, the guilty pleas are, of course, admissible under Fed. R. Evid. 801(d)(2) as admissions against a party opponent. As discussed more fully below, one theory of liability against Defendants is the failure to adequately warn Richard Smith's doctors by failing to provide them with information in the Neurontin label, as well as by other means, for use in off-label patients who had the same conditions that Mr. Smith had. The guilty plea is a statement that Warner-Lambert admits that it did not provide such directions, an admission that is inconsistent with the position Warner-Lambert now takes.

Many more precedents support the admission of a guilty plea, both against the party that entered the plea and in certain circumstances against civil co-defendants. A good starting point is *Miller v Holtzmann*, 563 F. Supp. 2d 54 (D.D.C. 2008), in which the court admitted one defendant's guilty plea to bid-rigging in a qui tam suit against multiple defendants. *Holtzmann* discusses the authorities under Fed. R. Evid. 803(22) and 801(d), and holds such guilty pleas are admissible. 563 F. Supp. 2d 83; *see also Scholes v. Lehmann*, 56 F.3d 750, 762 (7th Cir. 1995) (one defendant's plea agreement was admissible under Fed. R. Evid. 803(22) and established other defendants' liability); *Guillermety v. Gonzalez*, 491 F. Supp. 2d 199, 201 (D.P.R. 2006) (one defendant's guilty plea was admissible under Fed. R. Evid. 803(22) to establish all defendants' liability). In fact, courts have even admitted non-parties' guilty pleas against civil

defendants. *See, e.g., RSBI Aerospace, Inc. v. Affiliated FM Ins. Co.*, 49 F.3d 399, 401, 403 (8th Cir. 1995) (non-party employee's guilty plea and accompanying sworn statement were admissible against defendant employer in subsequent civil case); *Newby v. Enron Corp.*, 491 F. Supp. 2d 690, 703 (S.D. Tex. 2007) (non-party's guilty plea was admissible against defendants in subsequent civil case).

Many other cases are in accord. For example, in *In Re Edgewater Med. Ctr. v. Rogan.*, 332 B.R. 166 (Bankr. N.D. Ill. 2005), the court noted:

“In this Circuit, a criminal conviction based upon a guilty plea conclusively establishes for purposes of a subsequent civil proceeding that the defendant engaged in the criminal act for which he was convicted.” *Nathan v. Tenna Corp.*, 560 F.2d 761, 763 (7th Cir. 1977). Federal law no longer requires mutuality for the “offensive” use of collateral estoppel; application of such estoppel is entirely within the “broad discretion” of the trial court. *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 331, 99 S. Ct. 645, 58 L. Ed. 2d 552 (1979). The offensive use of criminal convictions by strangers to the original prosecution has been approved many times. *In re Teltronics, Ltd.*, 649 F.2d 1236, 1239 (7th Cir. 1981).

332 B.R. at 173.

While Defendants have decided that Warner-Lambert’s guilty pleas are not relevant to their defenses, they avoid the plain fact that the pleas are evidence that is relevant to Plaintiff’s theories of liability. Among Plaintiff’s theories is that Defendants were negligent for failing to adequately warn Richard Smith’s prescribing doctors of the increased risk of suicide-related events in patients who, as the Information describes, took Neurontin for “Unapproved Uses” such as pain. Failure to warn also is an element of other theories of liability, including fraudulent suppression of facts and breach of implied warranty of merchantability.

“Tennessee courts have long held that a manufacturer may be held strictly liable for failing to warn consumers of the dangers of a particular product at the time of sale. [Citations omitted.] Further, the General Assembly has also acknowledged that a failure to warn claim is a

valid basis for a product liability action in Tenn. Code Ann. § 29-28-102(6) . . . [citations omitted].” *Nye v. Cropscience, Inc.*, No. E2008-01596-COA-R3-CV, 2009 Tenn. App. LEXIS 697, at \*28 (Ct. App. Oct. 14, 2009) (reversing judgment for defendant in mesothelioma/asbestos product liability case and remanding case to trial court for new trial).

It is difficult to imagine evidence that is more probative of the negligent failure to warn than Warner-Lambert’s guilty admission that it failed to provide adequate instructions to doctors prescribing Neurontin off-label. Such prescriptions were not only foreseeable uses of the product that Defendants knew was associated with increased risks of suicide-related events and medical conditions that were not in the label, they were targeted uses. Warner-Lambert knew before Neurontin was ever approved that significant numbers of patients in pre-approval clinical trials sustained adverse events associated with suicidality and with the related effects of mental illness associated with suicide, such as depression. Before the FDA approved Neurontin for anything, there were 78 serious adverse events identified from the 2,048 patients exposed in trials, that is, more than five percent of the patients. This included seven reports of depression (each involving suicidal ideation), six of drug overdoses, and two suicide attempts. *Division of Neuropharmacological Drug Products Combined Medical-Statistical Review*, Oct. 13, 1993. More adverse events associated with suicidality between 1994 and 1996, the period covered by the guilty pleas, were documented in clinical pharmacology studies, monotherapy studies, and a STEPS trial. Defendants did not warn prescribing doctors of any these conditions or events in marketing Neurontin off-label or by misbranding Neurontin as charged in the information and admitted expressly and unequivocally as true in Warner-Lambert’s Plea Agreement. Fromson Decl., Ex. B.



The guilty plea, the information, and the plea agreement all provide evidence of Warner-Lambert's negligence, fraudulent suppression of facts, and breach of the implied warranty of merchantability. *See Federal Deposit Ins. Corp. v Finkielstain*, No. 91 Civ. 8020 (WK), 1993 U.S. Dist. LEXIS 12141 at \*6 (S.D.N.Y. Sep. 1, 1993) ("We therefore look to the allocution and guilty plea in order to determine to what extent the defendant's plea established facts which would now estop him from denying civil liability").

The plea in the underlying criminal case was negotiated between Warner-Lambert and the government over a two year period. The plea involved payment of restitution to the state and federal medical programs that had been induced to pay for the illegally marketed and misbranded, i.e., inadequately labeled drug. Such evidence has relevance beyond the mere words of the Information or guilty plea. As the court stated in *Miller v Holtzmann*:

Federal Rule of Criminal Procedure 11(f) mandates that before entering judgment on a guilty plea, a court must mak[e] such inquiry as shall satisfy it that there is a factual basis for the plea." Fed. R. Crim. P. 11(f). Because the court may not enter judgment without this factual basis, there is good reason to give preclusive effect to factual admissions made in Rule 11 proceedings. Though he avoids a contested trial, "a defendant who pleads guilty does not save the court as much work as does a party who, for example, stipulates to the truth of a fact in a civil trial." *Otherson*, 711 F.2d at 275 n.8. Moreover, because the court must conduct a Rule 11 inquiry, "the facts underlying a guilty plea are more reliable than those established only by stipulation." *Id.* Disincentives to litigate other than the truth of every fact alleged in an indictment may impact a defendant's decision to plead guilty. *See Haring v. Prosise*, 462 U.S. 306, 318-19, 103 S. Ct. 2368, 76 L. Ed. 2d 595 (1983) (describing possible pragmatic motivations for defendant's guilty plea). But as the Eleventh Circuit has observed, "[a] federal criminal defendant wishing to avoid both a trial and any collateral estoppel effects may ask for court permission to plead *nolo contendere*." *In re Raiford*, 695 F.2d 521, 523 (11th Cir. 1983). Moreover, a defendant may choose to plead only to particular portions of an indictment, thus limiting his plea's potential preclusive effect. *See, e.g., United States v. Podell*, 572 F.2d 31, 36 (2d Cir. 1978). These considerations suggest that factual admissions in a Rule 11 proceeding may broaden a guilty plea's preclusive effect beyond the mere abstract elements of the crime charged. Indeed, various other courts have approved the extension of pleas' collateral estoppel effects to defendants' accompanying factual admissions. *See, e.g., DeCavalcante v. Commissioner*, 620 F.2d 23, 24, 26, 28 & n. 10 (3d Cir. 1980) (approving Tax

Court's holding that defendant who had pleaded guilty to conspiracy to operate an illegal gambling enterprise could not deny connection with gambling activities admitted during Rule 11 hearing); *United States v. Electro-Therapeutics, Inc.*, No. 94 Civ. 4008, 1996 WL 137687, 2-3, 1996 U.S. Dist. LEXIS 2563, at 7-9 (S.D.N.Y. Mar. 6, 1996) (precluding defendant who pleaded guilty under general conspiracy statute from denying overt acts admitted during plea proceedings).

563 F. Supp. 2d at 79

What did Warner-Lambert admit unequivocally the truth of in the guilty plea?

First, Warner-Lambert admitted that it illegally marketed Neurontin without FDA approval for various off-label conditions, including *unapproved uses*. Fromson Decl., Ex. A, ¶¶ 9, 37-38. Richard Smith was prescribed Neurontin for his pain. His use of Neurontin was a foreseeable use in light of Warner-Lambert's marketing it off-label for such *unapproved use*.

Second, Warner-Lambert admitted that it did not provide prescribing doctors adequate directions in the Neurontin label for patients who took the medication for conditions not approved by the FDA. Richard Smith's physicians were never given the information that Warner-Lambert knew before FDA approval that over five percent of the clinical patients had adverse effects associated with increased suicidality; nor were the doctors informed of the increased signal of suicidality in off-label *other unapproved* uses and other patients that is reflected in the post-marketing adverse event data.

Third, Warner-Lambert admitted that it conducted market evaluations for the profit potential for these indications, Fromson Decl., Ex. A, ¶ 11, and determined not to seek FDA approval for those unapproved uses. *Id.* at ¶ 14. Defendant admitted that it used medical liaisons to promote Neurontin to doctors for unapproved purposes, including the message to doctors in the Boston area to "kick some ass . . . sell Neurontin on pain, . . . and everything that we can talk about." *Id.* at ¶ 24. Warner-Lambert effectively made doctors their sales agents by illegally promoting Neurontin at advisory board meetings, *id.* at ¶¶ 24, *et seq.*, buying Olympic tickets for

doctors who promoted Neurontin on Warner-Lambert's behalf, *id.* at ¶¶ 30-32, and organizing telephone conferences among doctors to spread the illegal promotion of Neurontin for off-label purposes. *Id.* at ¶¶ 33-36.

All of these illegal activities were designed to and did flood the medical community with information about Neurontin. All of these activities tend to prove that it is more probable than not that it was due to the illegal marketing of Neurontin that Richard Smith's doctors decided to prescribe Neurontin to him and did so because his doctors had not been provided adequate directions for use in the Neurontin label. The guilty pleas are evidence of such conduct and of negligence in marketing Neurontin without adequate instructions to physicians, conduct that began before the guilty pleas and that continued to bear fruit for Warner-Lambert and Pfizer without change right up until Mr. Smith died.

#### POINT IV

**DEFENDANTS' CLAIM OF PREJUDICE DOES NOT DISPLACE  
OR OUTWEIGH THE RELEVANT, PROBATIVE VALUE OF THE  
GUILTY PLEA AND RELATED EVIDENCE, WHOSE ADMISSION INTO  
EVIDENCE WOULD NOT VIOLATE DEFENDANTS' DUE PROCESS RIGHTS**

There is nothing unfair about allowing the jury to hear the details of a guilty plea that Defendants voluntarily entered and that is highly probative to the issues in this case. Under Fed. R. Evid. 403, relevant evidence may only be excluded "if its probative value is substantially outweighed by the danger of **unfair** prejudice . . ." Fed. R. Evid. 403 (emphasis added).

Defendants will have ample opportunity to explain the difference between off-label and fraudulent marketing in their opening and closing arguments, as well as in their proposed jury instructions. This is sufficient to negate any claim of unfair prejudice here. As Judge Fuld held in upholding the admissibility of guilty pleas: "To the claim that the jury will be unduly prejudiced by the introduction of a plea of guilt despite the opportunity to explain it away, we

content ourselves with the statement that [t]his underestimates the intelligence of jurors." *Ando v. Woodberry*, 8 N.Y.2d 165, 171 N.E.2d 520, 524 (N.Y. 1960).

It is not prejudicial to a defendant to admit into evidence a party's guilty plea to facts that are probative of some one or more of the contested issues simply because that party's interests may have changed after the guilty plea, and an inconsistent position now offers to it the potential for a different outcome in subsequent civil litigation. Thus, in *Miller v Holtzmann*, the court noted:

Second, any danger of unfair prejudice these documents may have posed to these co-defendants was substantially diminished by their redaction and by the limiting instructions given to the jury both immediately after the documents were introduced into evidence, (Apr. 10, 2007 PM Tr. at 100), and again in the Court's final instructions, (May 4, 2007 AM Tr. at 44-45). Defendants do not explain how these documents could be unfairly prejudicial to Bilhar, and it is not immediately obvious to the Court. The facts recited in the plea agreement and Rule 11 memorandum were certainly persuasive evidence, but particularly due to these documents' nature, it would not be unfair for the jury to assign great weight to Bilhar's voluntary admissions.

563 F. Supp. 2d at 82.

Moreover, it is not as if Pfizer and Warner-Lambert are strangers. Pfizer not only knew what it was buying when it purchased Warner-Lambert in approximately the year 2000, it continued to profit from Warner-Lambert's felony misconduct as Neurontin off-label sales skyrocketed thereafter.

On December 7, 2000, Pfizer Senior Vice President Feczko wrote to the Neurontin team and acknowledged that Warner-Lambert's criminal problems were Pfizer's to resolve: "*In late 1999, several months prior to the merger, a criminal Grand Jury investigation initiated by the Boston US Attorney's office . . . This investigation is ongoing.*" Fromson Decl., Ex. E.

The memo listed several measures to be taken to stop illegal off-label marketing. However, there were no plans to provide an adequate label to warn doctors of known risks of increased suicidality. Pfizer continued Warner-Lambert's misbranding.

Then, in April 2003, Pfizer officer John Marino wrote that even though Neurontin had come to Pfizer with "lots of legal problems," it had become "very special." Pfizer expected in 2000 that Neurontin would yield an additional \$1 billion in sales but in 2003 it was on track to yield an additional \$10 billion. His congratulatory message was sent to, among others, Atul Pande, Charles Taylor, and Lloyd Knapp, men who were key Warner-Lambert figures in the criminal marketing schemes and then became senior Pfizer officers and employees. Fromson Decl., Ex. F.

The profit figures are shocking, not only because of the money but also because over 90% of the sales were off-label. *See* attached Chart from October 28, 2008 Deposition of Charles King III, Ex. 1, Fromson Decl., Ex. G.

In short, Pfizer had full knowledge of Warner-Lambert's criminal problems, changed nothing, profited mightily, and employed at least some of the Warner-Lambert key personnel who were instrumental in the criminal scheme that led to the guilty pleas at issue here.

As noted in *United States v Dynamics Research Corp.*, Civil Action No. 03cv11965-NG, 2008 U.S. Dist. LEXIS 25354 at \*24 (D. Mass. Mar. 31, 2008), Pfizer is not prevented from disputing the underlying facts merely because Warner-Lambert has admitted criminal off-label marketing and misbranding. However, Pfizer also is not shielded from Warner-Lambert's criminal misconduct merely because it bought Warner-Lambert stock<sup>3</sup> to take over the company.

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<sup>3</sup> "Warner-Lambert Shareholders to Receive 2.75 Pfizer Shares for Each Warner-Lambert Share, Valued at \$98.31 Per Share . . . Pfizer Inc and Warner-Lambert Company today announced they have entered into a definitive merger agreement to create the world's fastest-growing major pharmaceutical company. Under terms of the merger agreement, Pfizer will exchange 2.75 shares of Pfizer common stock for each outstanding share of Warner-Lambert

*See UCAR Int'l v Union Carbide Corp.*, No. 00 CV 1338 (GBD), 2004 U.S. Dist. LEXIS 914 at \*39 ( S.D.N.Y. Jan. 26, 2004) (where court observed that changing controlling shareholders does not result in rebirth of corporation so as to allow successor to escape responsibility arising from criminal guilty plea of predecessor):

Where officers and directors use their corporation as an instrumentality to perpetrate a wrong, the subsequent purchase of the corporation from the wrongdoer does not insulate the corporation from liability. To do otherwise would “overlook the fact that one of the essential attributes of a corporation is its continuing existence as an entity despite changes in control and ownership.” *See, Holmes v. Bateson*, 583 F.2d 542, 560 (1st Cir. 1978).

2004 U.S. Dist. LEXIS 914 at \*39-40.

Indeed, if any distinction can be made from the evidence to separate the crimes and admissions of Warner-Lambert from the harvested profits Pfizer enjoyed from those crimes and admissions, the procedure is not to exclude Warner-Lambert’s guilty plea but to instruct the jury appropriately. *See United States v. Richardson*, 481 U.S. 166, 206 (1974); *United States v. Boone*, 437 F.3d 829, 838 (8th Cir. 2006) (“Where multiple defendants are tried together, the risk of undue prejudice is best cured through cautionary instructions to the jury”).

However, to exclude from evidence that Warner-Lambert expressly and unequivocally confessed as true that it failed to adequately warn the prescribing doctors of off-label patients such as Richard Smith of the risks of suicidality known to Warner-Lambert would be to allow that criminal both to lie to the jury about the true state of historical evidence and to continue to profit from its own wrongs. It would require that Plaintiff re-try the underlying facts of the violations of the criminal statutes to which Defendants fully admitted after a calculated two-year negotiation.

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stock in a tax-free transaction valued at \$98.31 per Warner-Lambert share, or \$90 billion, based on Pfizer's February 4 closing price of \$35.75. This represents a 34% premium over the average closing prices of Warner-Lambert during October 1999.”

Federal Rule of Evidence 803(22) offered Warner-Lambert a remedy that it did not take: if Warner-Lambert had wanted to exclude from this trial or any other trial the criminal admissions it was called on to make, it could have entered a plea of *nolo contendere*. The rule expressly provides for that option: “Evidence of a final judgment, entered after a trial or upon a plea of guilty, but not upon a plea of *nolo contendere*,” but Warner-Lambert did not take it. It should not now be allowed to act falsely in front of the Court and jury as if it had.

The Court presiding over Warner-Lambert’s guilty plea was obliged to determine from the record before accepting the plea and rendering a judgment of guilty that Warner-Lambert had indeed committed the acts it confessed to committing. The spectacle of Warner-Lambert now seeking to hide from a clean-breasted confession is summed up in *Miller v Holtzmann* as follows:

Yet the overt acts Bilhar admitted in the Rule 11 memorandum were nonetheless “essential to [its] plea” because they supplied a factual basis, without which the criminal court, under Rule 11, could not accept Bilhar's plea.<sup>4</sup>

563 F. Supp. 2d at 80. Footnote 14 from *Miller v. Holtzmann* states exactly what Pfizer and Warner-Lambert ignore:

Where a party assumes a certain legal position in a proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position, especially if it be to the prejudice of the party who has acquiesced in the position formerly taken by him. *Davis v. Wakelee*, 156 U.S. 680, 689, 15 S. Ct. 555, 39 L. Ed. 578 (1895).

That, however, is precisely what these Defendants ask this Court to help them do. The label that Warner-Lambert admitted in a criminal case was inadequate for doctors prescribing Neurontin off label was in all material respects the same label that accompanied Neurontin when Richard Smith’s doctors prescribed it to him and when he took it and took his own life.

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<sup>4</sup> 563 F. Supp. 2d at 80 n.14.

With regard to the due process argument, Defendants' lengthy discussion of *Philip Morris USA v. Williams*, 549 U.S. 346, 354 (2007), and *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003), is a red herring. These cases do not support a rule of exclusion that Defendants demand here. As the Supreme Court took pains to note in *Williams*, "Philip Morris . . . does not deny that a plaintiff may show harm to others in order to demonstrate reprehensibility. Nor do we." 549 U.S. at 354. Instead, these cases implicate the Court's responsibility for issuing proper jury instructions for punitive damages determinations. *See, e.g., White v. Ford Motor Co.*, 500 F.3d 963, 972-73 (9th Cir. 2007) (ordering new trial where judge failed to give proper "harm to nonparties" jury instruction). As the Sixth Circuit has succinctly explained, the Supreme Court's rule is that juries may consider harm to others "[w]hen assessing whether the defendant's behavior was sufficiently reprehensible to support an award of punitive damages," however, juries may not consider harm to others when assessing the amount of damages awarded. *Chicago Title Ins. Corp. v. Magnuson*, 487 F.3d 985, 1000 (6th Cir. 2007) (interpreting *Williams* and *Campbell*); *see also White v. Ford Motor Co.*, 500 F.3d 998, 972 (9<sup>th</sup> Cir. 2002) ("Where there is a significant risk that jurors will misapprehend the distinction, the court must upon request protect against that risk by `avoid[ing] procedure that unnecessarily deprives juries of proper legal guidance") (quoting *Williams*, 549 U.S. at 355); *Alaniz v. Zamora-Quezada*, 591 F.3d 761, 780 (5th Cir. 2009) (where proper jury instructions are issued, "a constitutional violation does not occur simply because evidence of harm to nonparties is admitted"). Thus, Defendants can address any concerns they have over the potential application of this evidence to damages at the time they submit their proposed jury instructions.



## **CONCLUSION**

Plaintiff respectfully requests that this Court deny Defendants' motion *in limine* to exclude all evidence of or references to Warner-Lambert Company LLC's guilty plea or any related government investigations or agreements. Such evidence is extremely relevant to salient issues in the case including Defendants' breach of their duty of care, and the probative value greatly outweighs any alleged unfair prejudice to Defendants by the admission of this evidence.

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Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on this the 27th day of April, 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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